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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,797	12/17/2003	Katherine Meyer Siegler	111828-00109	7390

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,797	SIEGLER, KATHERINE MEYER	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-93 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-93 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 2-5 and 11-15, insofar as the claims are drawn to a method for detecting or diagnosing prostate cancer in an individual, said method comprising determining the levels of MIF in the serum of the individual by immunoassay, classified, for example, in class 435, subclass 7.23.

Group II. Claims 6-10 and 16-22, insofar as the claims are drawn to a method for detecting or diagnosing prostate cancer in an individual, said method comprising determining the levels of MIF in the serum of the individual by measuring nucleic acid levels, classified, for example, in class 435, subclass 6.

Group III. Claims 2-5 and 11-15, insofar as the claims are drawn to a method for prognosticating prostate cancer in an individual, said method comprising determining the levels of MIF in the serum of the individual by immunoassay, classified, for example, in class 435, subclass 7.23.

Group IV. Claims 6-10 and 16-22, insofar as the claims are drawn to a method for prognosticating prostate cancer in an individual, said method comprising determining the levels of MIF in the serum of the individual by measuring nucleic acid levels, classified, for example, in class 435, subclass 6.

Group V. Claims 25-29 and 35-39, drawn to a method for monitoring the treatment of an individual with prostate cancer, said method comprising administering a pharmaceutical composition to the individual and determining the levels of MIF in the

serum of the individual by immunoassay, classified, for example, in class 435, subclass 7.23.

Group VI. Claims 30-34 and 40-46, drawn to a method for monitoring the treatment of an individual with prostate cancer, said method comprising administering a pharmaceutical composition to the individual and determining the levels of MIF in the serum of the individual by measuring nucleic acid levels, classified, for example, in class 435, subclass 6.

Group VII. Claims 49-52 and 58-62, insofar as the claims are drawn to a method for screening for an agent to capable of modulating the onset of prostate cancer, said method comprising exposing an individual to an agent and determining the levels of MIF in the serum of the individual by immunoassay, classified, for example, in class 435, subclass 7.23.

Group VIII. Claims 53-57 and 63-69, insofar as the claims are drawn to a method for screening for an agent to capable of modulating the onset of prostate cancer, said method comprising exposing an individual to an agent and determining the levels of MIF in the serum of the individual by measuring nucleic acid levels, classified, for example, in class 435, subclass 6.

Group IX. Claims 49-52 and 58-62, insofar as the claims are drawn to a method for screening for an agent to capable of modulating the progression of prostate cancer, said method comprising exposing an individual to an agent and determining the levels of MIF in the serum of the individual by immunoassay, classified, for example, in class 435, subclass 7.23.

Group X. Claims 53-57 and 63-69, insofar as the claims are drawn to a method for screening for an agent to capable of modulating the progression of prostate cancer, said method comprising exposing an individual to an agent and determining the levels of MIF

in the serum of the individual by measuring nucleic acid levels, classified, for example, in class 435, subclass 6.

Group XI. Claims 72-75 and 81-85, drawn to a method for monitoring the progression of prostate cancer, said method comprising determining the levels of MIF in the serum of the individual by immunoassay, classified, for example, in class 435, subclass 7.23.

Group XII. Claims 76-80 and 86-92, drawn to a method for monitoring the progression of prostate cancer, said method comprising determining the levels of MIF in the serum of the individual by measuring nucleic acid levels, classified, for example, in class 435, subclass 6.

3. Claims 1 and 23 are linking claims, linking the inventions of Groups I and II and also linking the inventions of Groups III and IV. Claims 24 and 47 are linking claims, linking the inventions of Groups V and VI. Claims 48 and 70 are linking claims, linking the inventions of Groups VII and VIII and also linking the inventions of Groups IX and X. Claims 71 and 93 are linking claims, linking the inventions of Groups XI and XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-XII are patentably distinct, each from the other, for the following reasons:

The inventions of Groups I and II are processes for detecting or diagnosing prostate cancer in an individual, albeit by materially different methods comprising different process steps, since the inventions of Group I involve determining the levels of MIF in the serum of the individual using an immunoassay, whereas the inventions of Group II involve measuring the amount of a nucleic acid molecule using methodology such as Northern blot analysis. In contrast to the inventions of Groups I and II, the inventions of Groups III and IV are process for prognosticating prostate cancer in an individual, albeit by materially different methods comprising different process steps. Such processes for prognosticating prostate cancer are necessarily materially different from processes for detecting and diagnosing prostate cancer, as practice of the former involves forecasting as to the probable outcome of the disease in a patient afflicted by the disease, the prospect as to recovery as indicated by the nature and symptoms of the case, whereas practice of the latter involves determining the presence of the disease in a patient not previously known to be afflicted by the disease. As such, although the inventions of Groups I and II and the inventions of Groups III and IV are practiced by determining the levels of MIF in the serum of the individual using an immunoassay or nucleic acid-based assay, the inventions necessarily involve the measurement of different endpoints, which provide some indication of the presence or the disease, or the alternatively the prospect as to recovery from the disease, and the establishment of different correlations between the levels of MIF in the serum of the individual and these different endpoints. The correlations of the levels of MIF in the serum of the individual and either the presence of the disease, or the prospect as to recovery from the disease are not expected to be the same; rather, it is expected that the levels of MIF in the serum of the individual may correlate more or less well with the presence of the disease, as opposed to the prospect as to recovery from the disease, and vice versa, so as to provide a better or poorer indication of those endpoints or the surrogate endpoints measured in their stead. Accordingly, the inventions having such different purposes or objectives have different criteria for success.

The inventions of Groups V and VI are processes for monitoring the treatment of an individual with prostate cancer, albeit by materially different methods comprising different

process steps. Thus, the inventions of Groups V and VI have different purposes or objectives than the inventions of any of the previously mentioned inventions; and while the inventions of Groups V and VI comprise determining the levels of MIF in the serum of an individual, the inventions further comprise administering a pharmaceutical composition to the individual before making such a determination. Accordingly, the inventions of any of Groups I-VI are each materially different from the others, and comprise different process steps.

Similarly, the inventions of Groups VII and VIII are materially different processes for screening for an agent to capable of modulating the onset of prostate cancer; although the inventions comprise determining the levels of MIF in the serum of an individual, they further comprise exposing the individual to an agent before making that determination. As with the other pairs of inventions, the inventions of Groups VII and VIII are different from one another, as each comprises determining the levels of MIF in the serum of an individual using materially different methods comprising different active steps. While the inventions of Groups IX and X are similar, they are processes for screening for an agent to capable of modulating the progression, as opposed to the onset of prostate cancer. As such, the inventions of Groups IX and X are necessarily practiced by exposing an individual afflicted with the disease to an agent and then determining the levels of MIF in the serum of the individual, whereas the inventions of Groups VII and VIII are necessarily practiced by exposing an individual *before* the onset of the disease and then determining the levels of MIF in the serum of the individual.

The inventions of Groups XI and XII are processes for monitoring the progression of prostate cancer, albeit by determining the level of MIF in the serum of patients afflicted by the disease using different methodology. Accordingly, the inventions of Groups XI and XII have purposes or objectives that differ from those of any of the aforementioned groups of inventions. Moreover, the inventions of Groups XI and XII are materially different, or comprise process steps that differ from the other inventions.

For these reasons, any of the inventions of Groups I-XII are patentably distinct from the others.

Because any of the inventions of Groups I-XII are patentably distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore,

the inventions of Groups I-XII have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to any of the inventions of Groups I-XII, an examination of more than one would constitute a serious burden.

Since the inventions of Groups I-XII have been shown to be patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
July 6, 2006